

K964630

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

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Device: Trade/Proprietary Name: GLUCOMETER ELITE® Blood
Glucose Meter
Common/Usual Name: Blood Glucose Meter
Document Control Number: K96 _____

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 CGA (Glucose Oxidase, Glucose)

Predicate Device: GLUCOMETER ELITE® Blood Glucose Meter
Manufactured by Kyoto Daiichi Kagaku Co., Ltd.: of Kyoto,
Japan

Device Description: The GLUCOMETER ELITE System consists of an
electrochemical method-based meter and dry reagent sensors (test
strips) designed for testing glucose by persons with diabetes or by
healthcare professionals in the home or in healthcare facilities.

Intended Use: The GLUCOMETER ELITE Blood Glucose Meter is for the
Self-Monitoring of Blood Glucose as an adjunct to the care of
persons with diabetes.*

* "Consensus Statement on Self-Monitoring of Blood Glucose," *Diabetes Care*, Vol. 10, No. 1, January-February 1987, pp. 95-99.

4. Safety and Effectiveness

The EDGE/VISTA systems with the system enhancement package are similar in technological characteristics and intended use to EDGE/VISTA systems with standard or high performance gradients. The following chart has been created to demonstrate their substantial equivalence.

SUBSTANTIAL EQUIVALENCE CHART

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Computer Subsystem	Similar display/database computer, monitor and Ethernet communications systems. Ethernet communications link complies with DICOM v3.0 to allow image transfer to other MR, CT, Nuclear, workstation systems and cameras. Optional packages available for increased image reconstruction rates.	Display/Database computer and scan reconstruction hardware connected together by a dedicated Ethernet communications system. Allows for simultaneous scanning and image reconstruction/ manipulation. Single monitor for system operation and image reviewing. Second Ethernet interface for communication with systems on the external network. (See K931544)
Image Storage Short Term: Archival:	Same Same	Magnetic Disk Optical Disk (See K931544)